Please add the folowing new claim:

-- 12. A pharmaceutical preparation which provides a dosage form of Tamoxifen, wherein the dosage form comprises at least 1.5 g/ml of Tamoxifen Citrate, in the absence of a complexing agent, in a pharmaceutically acceptable solution which ~~is~~ can be administered orally. --

REMARKS

Claims 1 and 2 are amended and claim 12 is added, hereby. Claims 1 - 12 are now pending.

The only rejection pending in this application is the rejection of claim 1 under 35 USC 103(a) over WO '506. This rejection is again respectfully traversed.

Claim 1 has been amended to incorporate a limitation of the allowable dependent claims; specifically a component of the solution recited in claim 2 is now recited in claim 1. This embodiment is not disclosed or suggested in WO '506.

The amendment to claim 1 is made in order to expedite the allowance of this application. It remains Applicant's position, however, that WO '506 cannot make out a *prima facie* case of obviousness of claim 1. Therefore, with some changes, claim 1 is also recast as new claim 12. In this claim, it is made clear that the solution has to be one that is (1) pharmaceutically acceptable, and (2) administered orally. The new claim does not actually raise any new issues that would need further search or consideration, but only addresses the issue currently of record: does WO '506 disclose or suggest an orally administratable dosage form of Tamoxifen?

As is set forth in Applicant's previous response, the answer is "no", because NMF is not pharmaceutically acceptable for oral administration. See Rowinsky et al., *J. Natl. Cancer Inst.*, 80(9):671-678 (1988), which concludes that high enough levels of NMF to be chemotherapeutic are associated with "intolerable hepatic, gastrointestinal, and constitutional toxic effects."

See last paragraph of the article, and the Discussion section, generally.

There must be some motivation for one of skill in the art to derive the invention at hand from the prior art. In this case, the motivation is lacking, because of the unacceptability of NMF in oral medications.

It is an unfortunate choice of wording in the Office Action that unacceptability for human patients in the United States does not preclude acceptability for animals and use in third world countries. It is hoped that what is meant is that under circumstances of extremely limited resources the choice of using more risky materials is allowable where the alternative is no treatment at all. The rejection states that "...the fact that they may not be desirable or even suitable for that [oral] purpose does not mean the use is not obvious...". On the contrary, this fact goes to the heart of an obviousness determination: whether one of skill in the art would be motivated to use what is in the prior art to develop the present invention. Quite clearly, one of skill in the art developing an oral solution of Tamoxifen would not choose NMF as the solvent, because of NMF's known toxic side effects when administered orally.

Accordingly, Applicant does not believe there is a reasonable basis to reject claim 1 (now claim 12) as obvious over WO '506. In the interest of time and expense, it is respectfully requested that claim 12 be entered into this application and allowed along with claims 1 - 11. Claim 12 does not raise any new issues or new matter, and in any event puts the application in better form for appeal, if necessary.

Should the Examiner believe any issues remain that could be resolved by telephone, he is invited to contact the undersigned at the number listed below.

Favorable action is solicited. In the event any fees are required with this paper, please charge our Deposit Account No. 02-2334.

Respectfully submitted,

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